

The subject matter claimed is:

1. A gastro-retentive dosage form of levodopa for oral administration to a patient in need thereof, said dosage form comprising

5 (a) a tablet comprising a therapeutically effective amount of levodopa, a binder, and a pharmaceutically-acceptable gas-generating agent capable of releasing carbon dioxide upon contact with gastric juice, and

(b) an expandable, hydrophilic, water-permeable and substantially gas-impermeable, membrane surrounding the tablet, wherein the membrane expands as a result of the release of
10 carbon dioxide from the gas-generating agent upon contact with the gastric juice, whereby the dosage form becomes too large to pass into the patient's pyloric sphincter.

2. The dosage form of claim 1, further comprising a covering for containing the dosage form, wherein the covering disintegrates upon contact with gastric fluid.

15 3. The dosage form of claim 2, wherein the covering is a dry-fill capsule.

4. The dosage form of claim 1, wherein the levodopa is present in an amount of about 10% to about 50% of the total tablet weight.

20 5. The dosage form of claim 1, wherein the tablet further comprises carbidopa.

6. The dosage form of claim 1, wherein the membrane comprises polyvinyl alcohol.

25 7. The dosage form of claim 6, wherein the polyvinyl alcohol is present in the membrane at between 40% and 85%.

8. The dosage form of claim 1, wherein the tablet comprises levodopa and carbidopa in a weight ratio of between about 4-to-1 and about 10-to-1 levodopa to carbidopa.

9. The dosage form of claim 1, wherein the gas-generating agent is selected from the group consisting of sodium bicarbonate, sodium carbonate, sodium glycine carbonate, potassium carbonate, calcium carbonate, magnesium carbonate and mixtures thereof.
- 5 10. The dosage form of claim 9, wherein the gas-generating agent is sodium bicarbonate.
11. The dosage form of claim 1, wherein the binder is selected from the group consisting of a polyoxyethylene stearate, a poloxamer, a polyethylene glycol, a glycerol palmitostearate, a glyceryl monostearate, a methylcellulose and a polyvinyl pyrrolidone.
- 10 12. The dosage form of claim 11, wherein the binder is selected from the group consisting of Myrj 52, Lutrol F68, PEG 3350, a methylcellulose and a polyvinyl pyrrolidone.
13. A method of making a gastro-retentive dosage form of levodopa, which method
15 comprises
- (a) forming a tablet comprising levodopa, a binder and a pharmaceutically-acceptable gas-generating agent,
 - (b) surrounding the tablet with an expandable, hydrophilic, water-permeable and substantially gas-impermeable membrane, and
 - 20 (c) sealing the membrane to retard the escape of gas from within the sealed membrane.
14. The method of claim 13, further comprising the step of encapsulating the sealed membrane within a covering that disintegrates without delay upon contact with gastric fluid.
- 25 15. The method of claim 14, wherein said covering is a dry-fill capsule.
16. The method of claim 13, wherein the tablet formed in (a) also comprises carbidopa.
- 30 17. The method of claim 13, wherein the levodopa is present in an amount of about 10% to about 50% of the total weight of the tablet formed in (a).

18. The method of claim 13, wherein the membrane comprises polyvinyl alcohol.
19. The method of claim 18, wherein polyvinyl alcohol is present in the membrane at
5 between 40% and 85%.
20. The method of claim 13, wherein the tablet formed in (a) comprises levodopa and carbidopa in a weight ratio of between about 4-to-1 and about 10-to-1 levodopa to carbidopa.
- 10 21. The method of claim 13, wherein the gas-generating agent is selected from the group consisting of sodium bicarbonate, sodium carbonate, sodium glycine carbonate, potassium carbonate, calcium carbonate, magnesium carbonate, and mixtures thereof.
22. The method of claim 21, wherein the gas-generating agent is sodium bicarbonate.
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23. The method of claim 13, wherein the binder is selected from the group consisting of a polyoxyethylene stearate, a poloxamer, a polyethylene glycol, a glycerol palmitostearate, a glyceryl monostearate, a methylcellulose, and a polyvinyl pyrrolidone.
- 20 24. The method of claim 23, wherein the binder is selected from the group consisting of Myrj52, Lutrol F68, PEG 3350, Precirol ATO5, a methylcellulose, and a polyvinyl pyrrolidone.
25. The method of claim 24, wherein the binder is selected from the group consisting of Myrj52, Lutrol F68 and PEG 3350.
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26. The method of claim 13, wherein the forming step comprises fluid bed granulation or melt granulation.
27. A method of treating a patient suffering from Parkinson's disease comprising orally
30 administering to said patient the gastro-retentive dosage form according to claim 1.

28. An article of manufacture comprising the dosage form according to claim 1, packaging material containing the dosage form and a label or insert indicating instructions for use of the dosage form for treatment of Parkinson's disease.